K042827

**SECTION 2 - 510(K) SUMMARY**
**September 23, 2004**

JAN - 6 2005

**Name and Address of Applicant**
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
Serrah Namini
90 Icon St.
Foothill Ranch, Ca 92610
(949) 580-1555 Ext 4401
Fax: (949) 580-1550

Trade Name: Cardiofax CE
Common Name: Electrocardiograph and ECG
Classification Name: The device has been classified as Class II by the Division of Cardiovascular, Respiratory, and the Cardiovascular Device Classification Panel under 21 CFR Part 870.2340 "Electrocardiograph" per 74 LOS.

Cardiofax CE, PEA-1110K series, is a portable ECG acquisition terminal, which measures 12 lead ECG waveforms. The measured ECG waveforms are analyzed and transferred to an ECG data filing system thru a wireless LAN. The device features a built-in battery.

Nihon Kohden's PEA-1110K series is intended for medical purposes to process the electrical signals transmitted through electrocardiograph electrodes and to produce a visual display and/or transmit data to a remote printer and/or a computer of the electrical signals produced by the heart. Measurements and waveforms and diagnostic information are offered to physicians on an advisory basis.

The new device offers a full page file with 1 to 12 channel selectable formats, keyboard data entry, battery and AC power operation with internal battery recharging circuit and waveform analyses with measurements, all of which are features of the predicate device. The new device provides a waveform display and PC memory card option, all comparable to the predicate ECG-9130K.

While the device is equivalent, there are a few changes in the new device as compared to the predicate. The new device is smaller, lighter and more compact than the predicate device. In addition, the new device does not include a printer and uses a different type of battery. These changes have been made to address user preferences and do not affect the indication for use or safety and efficacy of the new device.

The device complies with the IEC 60601-1 standard and sub-clause 56.3(c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables. .

The device was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the PEA-1110K series is substantially equivalent to our predicated ECG-9130K.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2005

Nihon Kohden America, Inc.
c/o Ms. Serrah Namini
Regulatory Affairs
90 Icon St.
Foothill Ranch, CA 92610

Re: K042827
Trade Name: Cardiofax CE, PEA-1110K series
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: September 23, 2004
Received: October 12, 2004

Dear Ms. Namini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**G. Indications for Use Statement**

510(k) Number (if known): _____

Device Name: Cardiofax CE; PEA-1110K Series

Indications for Use: The Cardiofax CE electrocardiograph is intended for medical purposes to process the electrical signals transmitted through two or more electrocardiograph electrodes to produce a visual display and/or wireless transmission of data to a remote printer and/or computer.

For non-interpretive applications, the device is intended for use with a full range of patient populations as determined by a clinician. The devices also provide an interpretive ECG program intended for use with patients age 3 years to adult.

The interpretation program is intended to provide an assessment of ECG waveform rhythm and morphology to assist the physician in diagnosis. Assessments provided by the interpretation program are not intended as the sole basis for diagnosis. All assessments provided by the interpretation program are recommended for review by qualified physicians trained in electrocardiography.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

**CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)**

K042827

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number